GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:575
ANSWERED ON:17.07.2002
LICENSES FOR DNA DRUGS
YEMPARALA VENKATESWARA RAO

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government have directed the drug controllers not to issue licenses for genetically modified drugs;and

(b) if so, the reasons for centralizing licensing system for DNA drugs?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a)&(b): No, Sir. Vide Gazette Notification No. G.S.R. 1039 dated 5th December, 1989, issued by Ministry of Environment and Forests for environment impact issues etc. GEAC clearance of recombinant derived products including drugs and pharmaceuticals is required. As per the Notification, local manufacturers of DNA derived drugs are required to take RCGM (Review Committee of Gene Manipulation) approval for carrying out pre-clinical animal experimentation with their product, based on examination of molecular characterization, gene manipulation techniques, impurity profile, and immuno chemical properties etc. The applicants are then required to submit the application alog with the data to DCG (I) under Rule 122B and as per Schedule `Y` of Drugs and Cosmetics Acts and Rules thereunder for undertaking human studies as well as approval. The applicant also makes application to Genetic Engineering Approval Committee (GEAC) in Ministry of Environment.

As per rules, drug approved for import/manufacture is considered as New Drug for a period of 4 years.

After examination and evaluation of the data from the expert panel and GEAC clearance from Ministry of Environment and Forests approval is granted to the applicants who in-turn obtain the Licence from State Licensing Authority.